UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,840	01/20/2006	Fabrizio Samaritani	7541-6	4228

30565 7590 04/22/2008

WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER	
GUPTA, ANISH	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
04/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,840	SAMARITANI ET AL.	
	Examiner	Art Unit	
	ANISH GUPTA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-53,56-64,72-80,82-89 and 189-211* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-53,56-64,72-80,82-89 and 189-211* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3-17-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-22-08 has been entered.

2. The amendment filed, 3-19-08 is acknowledged. Claims 198-211 were added. Claims 46, 50, 61, 62, 72, 73, 74, 87, and 194 were amended. Claims 46-53, 56-64, 72-80, 82-89, 189-211 are pending in this application.

3. All rejections made in the previous office action and not cited herein are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and

invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 46-53, 56-64 and 198-211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al. (US2002/0165146).

The claims are drawn to a formulation cresol, FSH and a surfactant selected form poloxamer 188, poloxamer 217, poloxamer 237, poloxamer 238.

The reference teaches a formulation comprising FSH. Specifically, the reference discloses formulation of FSH with cresol or phenol (see page 27, claim 1). The reference also states that that FSH is in a concentration between 5.0 micorgrams/ml to 2 milligram/ml (See page 11, paragraph [0097]). The cresol is in the concentration of 23 millimolar to 35 millimolar (see page 11, para [0098]). The reference also disclose that other additives such as tween 20, and pluronic F68, poloxamer 184 or 188 can be added to reduce aggregation (see page 12, para [100]). The reference discloses the use of isotonicity agents such as sucrose and methionine (see paragraph [0046]). The pH of the formulation is between 6.8 and 7.8 (see page 11, para [0099]). The reference states that the FSH can be recombinently produced and can be from urinary sources (see page 10, para [0094]). While the reference does not specifically teach a formulation with cresol, FSH and poloxamer, it would have been obvious to add poloxmer 184 or 188 to a formulation of cresol and FSH so as to prevent reduced aggregation.

As for the dosages claimed, the MPEP states "[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

workable ranges by routine experimentation. . . .The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." See MPEP 2144.05. Here, the reference disclose the use of various concentrations for the FSH and cresol. It would have been obvious to optimize the optimum dosage for each component.

5. Claims 72-80 and 82-89, 189-197 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al. as applied to claims 46-53, 56-64 and 198-211 above, and further in view of Skrabanja et al. (US 5929028).

The claims are drawn to a formulation cresol, FSH and a surfactant selected form poloxamer 188, poloxamer 217, poloxamer 237, poloxamer 238.

The reference of Hoffman et al. has been discussed supra. The reference implies that FSH can be used alone or in combination with other gonadotropins (see page 3, paragraph [0028]). The difference between the US pg pub and the instant application is that the US pg pub doe not disclose the use of LH.

However, Skrabanja et al. teaches that combination of FSH with LH has been used to stimulate ovarian growth (see col. 1, lines 15-30). The reference specifically teaches formulations of FSH and LH (see col. 6). The reference disclose both liquid formulation of liquid formulations that can be freeze dried (see col. 6). The reference disclose that the formulations can have numerous additives such as sucrose (col. 5, lines 1-15) and non ionic surfactant such tween 20 or pluronic f123 (see col. 5, lines 23-34). It would have been obvious, therefore, to use a combination of FSH and LH because the combination formulation has been used for stimulation of ovarian growth. There would have been a reasonable expectation of success because the Skrabanja et al. teach many of the

same components in a formulation comprising LH and FSH as taught in Hoffman. Furthermore, Hoffman implies that the FSH their invention can be used in combination with other gonadotropins.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/

Primary Examiner, Art Unit 1654